

Appl. No. : 10/659,941  
Filed : September 11, 2003

### REMARKS

This Amendment is submitted in response to the Office Action mailed July 14, 2004. Claims 1-52 are pending. Claims 1, 2, 11, 12, 22, 23, 32, 33, 42, and 43 have been amended. Support for the amendments is provided in the original claims as filed and throughout the specification. For example, support for the amendments can be found at Paragraphs [0004], [0020], and [0023] of the specification. Claims 1-52 are pending and are presented for examination. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

#### **Claims 1-52 are definite under 35 U.S.C. §112, second paragraph**

Claims 1-52 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the term “68%” in Claims 2, 12, 33, and 43 was objected to. Similarly, the term “concentrated” in claims 1, 11, 22, and 42 was objected to as rendering the claims indefinite.

Claims 2, 12, 23, 33 and 43 have been amended to clarify that the term “68%” refers to “68% by weight.” Claims 1, 11, 22, 32, and 42 have been amended to specify that the term “concentrated” reflects a beta-glucan composition having a concentration greater than 7% by weight, which is the naturally occurring concentration of beta glucan in oat bran. Support for these amendments can be found throughout the specification. Support for the “by weight” clarification and the “7% by weight” limitation can be found at, for example, paragraph [0004] of the specification.

Applicants assert that, in view of the aforementioned amendments, the claims possess clarity and definiteness to particularly point out and distinctly claim the subject matter they regard as the invention. Withdrawal of the rejections under 35 U.S.C. §112, second paragraph is therefore requested.

#### **Claims 1-52 are novel under 35 U.S.C. §102(b) in view of Misaki et al. (U.S. Patent No. 4,769,363)**

Claims 1, 3-11, 13-18, 22, 24-32, 34-42, and 44-50 were rejected under 35 U.S.C. §102(b) as being anticipated by Misaki et al. (U.S. Patent No. 4,769, 363) (the ‘363 patent). Under 35 U.S.C. § 102(b), a claim is anticipated only if the reference teaches each and every limitation of the claim. M.P.E.P. § 2131. Claims 1, 9, 11, 22, 31, 32, 41, 42, and 53 have been

amended to clarify that the mixed linkage (1→3)(1→4) beta linkage has a mixed  $\beta(1,3)(1,4)$  linked glucopyranosyl backbone. Each element as set forth in the claims, as amended, is not found in the '363 patent. Accordingly, Applicants respectfully submit that Claims 1, 3-11, 13-18, 22, 24-32, 34-42, and 44-50 are not anticipated by the '363 patent and request withdrawal of the PTO's rejection under 35 U.S.C. §102(b).

Claim 1 and the claims depending therefrom recite a mixed linkage, (1→3)(1→4) beta-glucan composition having a mixed  $\beta(1,3)(1,4)$  linked glucopyranosyl backbone. The '363 patent, by contrast, recites a  $\beta$ -1,3-glucan derived from a microorganism. Notably, the '363 patent does not disclose or suggest the mixed linkage (1→3)(1→4) form of beta glucan as is presently claimed. The '363 patent clarifies that the backbone of the disclosed microorganism-derived beta glucan consists of beta-1,3-linked D-glucopyranose residues and noted that the backbone lacked any 1,4 linkages. See Col. 3, lines 25-33 of the '363 patent. By contrast, the specification and claims, as amended, of the present application specifically makes clear that the term "beta-glucan" is defined as a glucan with a mixed  $\beta(1\rightarrow3)(1\rightarrow4)$ -linked glucopyranosyl backbone. See Paragraph [0020] of the specification.

One of skill in the art would readily appreciate that a beta-glucan derived from a microorganism varies greatly both structurally and functionally from a mixed linkage, (1→3)(1→4) beta glucan derived from, for example, a cereal grain. The PTO opines that the source from which the beta-glucan is obtained does not limit the claimed composition. Applicants respectfully disagree. The beta-glucan described in the '363 patent is of bacterial origin and is replete with side-chains not found in beta-glucans of grain origin. It is well known that bacterial (as well as yeast) beta-glucans differ substantially from grain beta-glucans not only in structure but, also, in chemical, physical, biochemical, and pharmacological properties. For example, the '363 compounds are described as having strong anti-oncotic activity; however, no such activity is recognized for grain beta-glucans.

The PTO fails to appreciate that beta-1,3-glucan is an entirely different compound possessing entirely different properties than the presently claimed mixed linkage (1→3)(1→4) beta glucan. Just as all starches, or gums, or all proteins or sugars are not the same, so all  $\beta$ -glucans are not the same, but rather they differ dramatically when the linkages are changed. Because the '363 patent fails to teach each and every limitation of the claimed invention, namely

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the mixed linkage (1→3)(1→4) beta glucan limitation, the reference does not anticipate the claimed invention. Thus, applicants request that the rejection of these claims be withdrawn.

**Claims 1-52 are non-obvious under 35 U.S.C. §103(a) in view of Misaki et al. (U.S. Patent No. 4,769,363)**

Claims 1-50 were rejected under 35 U.S.C. §103(a) as being unpatentable over Misaki et al. (U.S. Patent No. 4,769,363) (the '363 patent). A *prima facie* case of obviousness is established when three basic criteria are met. M.P.E.P. §2142. First, the prior art must suggest the desirability of the claimed invention. Second, the prior art must create a reasonable expectation of success in the practice of the invention under consideration. Third, all limitations of the claims of the present application must be taught or suggested. If the prior art fails to meet one or more of these criteria, a *prima facie* case of obviousness cannot be asserted. Applicants submit that the contrasts between the present invention and the '363 patent are significant and the reference is not sufficient to support a *prima facie* case of obviousness.

According to the PTO, the difference between the claimed composition and the composition disclosed in the '363 is that the '363 patent is silent with respect to the concentration in percent of beta-glucan. The PTO further opines that it would have been obvious to one having ordinary skill in the art to prepare the beta glucan compositions in '363 with the claimed percent concentrations of beta glucan to be used as chemicals, food products, or pharmaceuticals. However, the PTO's assessment with respect to alleged obviousness is mistakenly based on the assumption that the beta glucan described in the '363 is the same beta glucan claimed in the present invention. As detailed above, the beta glucans are markedly different.

In order to establish a case for obviousness, the PTO must, *inter alia*, cite prior art that teaches or suggests all the claim limitations. See M.P.E.P. § 2143.03. Contrary to the position taken by the PTO, the '363 patent does not disclose or teach the claimed mixed (1→3)(1→4) linkage beta glucan compositions. As discussed above in response to the §102 rejection, the '363 patent describes a beta glucan having backbone consisting of beta-1,3-linked D-glucopyranose residues. The microorganism-derived beta glucan lacks any 1,4-linkage in the backbone. By contrast, the present invention discloses compositions comprising a beta glucan having a mixed  $\beta(1\rightarrow3)(1\rightarrow4)$  linked glucopyranosyl backbone. Because the '363 patent does not disclose a beta

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glucan having a mixed  $\beta$ -(1 $\rightarrow$ 3)(1 $\rightarrow$ 4) linked glucopyranosyl backbone, it fails to teach each and every limitation of the claim and therefore cannot render the claimed invention obvious.

Additionally, a *prima facie* case for obviousness is established only when the Examiner provides references that would lead one of ordinary skill in the art to believe that he or she would have a reasonable expectation of success in practicing the claimed invention in view of the cited art. See In re Merck & Co., Inc., 231 U.S.P.Q. 375 (Fed. Cir. 1986); M.P.E.P. §2143.02. The beta glucan described in the '363 patent is not identical or interchangeable with the presently claimed beta glucan compositions. The structure, function, and activity of the beta glucans are likewise dissimilar. A skilled artisan, therefore, would have no reasonable expectation of success in substituting a glucan having a mixed  $\beta$ (1,3)(1,4) linked glucopyranosyl backbone as is presently claimed for the beta-1,3-linked glucan described in the '363 patent. Finally, the PTO has pointed to no motivation to modify the '363 patent to arrive at the claimed compositions.

In view of the deficiencies discussed above, '363 is not sufficient to support a *prima facie* case of obviousness. Therefore, Applicants request withdrawal of this rejection.

#### CONCLUSION

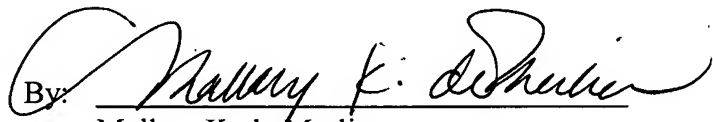
In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Nevertheless, the PTO is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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